

Voluntary - Public

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MRL changes in Acequinocyl Prohydrojasmon Pencycuron Brotizolam and Rifaximin

Report Categories:

Sanitary/Phytosanitary/Food Safety

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Report Highlights:

On May 22, 2009, Government of Japan announced proposed changes to the MRLs for Acequinocyl, Prohydrojasmon, Pencycuron, Brotizolam and Rifaximin. The domestic comment period is closed already but MHLW will then notify these proposed changes to the WTO/SPS committee, which will provide a chance for public comments to be submitted on this subject.

General Information:

On May 22, 2009, Government of Japan announced proposed changes to the MRLs for Acequinocyl, Prohydrojasmon, Pencycuron, Brotizolam and Rifaximin. The domestic comment period is closed already but MHLW will notify these proposed changes to the WTO/SPS committee, which will provide a chance for public comments to be submitted on this subject.

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Please also consider copying the U.S. Embassy, Tokyo at agtokyo@usda.gov on your comments in order for them to be considered as part of the official U.S. Government comments to the WTO.

Pesticides and Other Contaminants:
Establishment of Maximum Residue Limits for Agricultural Chemicals in Food

Purpose and Background

The Ministry of Health, Labour and Welfare (MHLW) is going to develop the compositional specification for food.

Under the provisions of Article 11, Paragraph 1 of the Food Sanitation Law, the MHLW is authorized to establish residue standards (maximum residue limits: MRLs) for pesticides, feed additives, and veterinary drugs (hereafter referred to as just “agricultural chemicals”) that may remain in foods. Any food for which standards are established pursuant to the provisions is not permitted to be marketed in Japan unless such food complies with the established standards.

On May 29, 2006, the MHLW introduced the positive list system for agricultural chemicals in food.* Basically, all foods distributed in the Japanese marketplace are subject to regulation based on the system.

This time the MHLW has newly established MRLs (draft) for some food commodities as well as has comprehensively reviewed the current MRLs. This activity is targeted to five chemicals: Acequinocyl (pesticide), Prohydrojasmon (pesticide), Pencycuron (pesticide), Brotizolam (veterinary drug), and Rifaximin (veterinary drug). Details are given below.

Note: The positive list system was established based on the 2003 amendment of the Food Sanitation Law. The system aims to prohibit the distribution of any food in the Japanese marketplace if it contains agricultural chemicals at amounts exceeding a certain level (0.01 ppm) specified under the Law.

Outline of revision

<Pesticides>

Acequinocyl (acaricide)

This chemical is already permitted for use in Japan. This time the Ministry of Agriculture, Forestry and Fisheries (MAFF) will expand the scope of target crops for which the use of the chemical is permitted. In response to the MAFF's action, the MHLW has newly established MRLs (draft) for some crops and has comprehensively reviewed the existing MRLs. For draft MRLs, see Attachments 1-1.

Prohydrojasmon (plant growth regulator)

This chemical is already permitted for use in Japan. MAFF will expand the scope of target crops for which the use of the chemical is permitted. In response to MAFF's action, the MHLW has newly established MRLs (draft) for some crops. For draft MRLs, see Attachments 1-2.

Pencycuron (fungicide)

This chemical is already permitted for use in Japan. A foreign business has filed an application with the MHLW for the establishment of additional MRLs for the substance, based on the Guideline for Application for Establishment and Revision of Maximum Residue Limits for Agricultural Chemicals Used outside Japan, published on 5 February 2004. In response to the application, the MHLW has newly established MRLs (draft) for some crops and has comprehensively reviewed the existing MRLs. For draft MRLs, see Attachments 1-3.

The existing MRLs for Acequinocyl, Prohydrojasmon and Pencycuron appear in either of the MRLs List (the Item 6, Section A "General Compositional Standards for Food," Part I "Food" of the Specifications and Standards for Food, Food Additives, Etc.) or Provisional MRLs List (Item 7, Section A), according to food commodities. These MRLs have been modified as necessary. Finalized MRLs for these chemicals will be placed on the MRLs List in Item 6, and the MRLs currently placed in Item 7 will be deleted.

<Veterinary drug>

Brotizolam (Inappetence improvement assistance agent):

This chemical is permitted for use in Japan. MAFF has reassessed a drug product whose effective ingredient is Brotizolam. This is on the basis of the legal requirement stating that veterinary drugs, once approved, must be reassessed every six years. In response to the MAFF's assessment, the MHLW has reviewed the existing MRLs for the substance.

The MRLs for this chemical currently appear in the Provisional MRLs List (Item 7 of Section A "General Compositional Standard for Food," Part 1 "Food" in the Specifications and Standards for Food, Food Additives, Etc). The substance will be placed in Item 5, which specifies substances that shall not be included in food. The MRLs currently placed in Item 7 will be deleted. After the revision takes effect, the substance will not be permitted to be included in any food. However, for certain foods, MRLs will be established and placed in the MRLs List in item 6. The certain foods refer to cattle muscle, fat, liver, kidney, other edible offal, and milk. For draft MRLs, see Attachment 1-4.

Rifaximin (antimicrobial)

This chemical is not permitted for use in Japan. The MHLW has comprehensively reviewed the MRLs for this substance that had been established at the time of the introduction of the new system. The current MRLs were provisionally established at the introduction of the system, based on EU standards. However, the MHLW is going to withdraw these standards, which currently appears in the Provisional MRLs List (Item 7, Section A "General Compositional Standards for Food," Part I "Food" of the Specifications and Standards for Food, Food Additives, Etc.). The MHLW has judged that it is very difficult to set standards based on sound science because we were not able to confirm the exact situation at the time of approval in the EU due to lack of necessary information on residue. After the revision takes effect, the substance will not be permitted to remain in any food, based on the provision of Item 1 in Section A stipulating that food shall not contain any antimicrobial or synthetic antibacterial. See Attachment 1-5.